REMARKS

This Amendment is in response to the Examiner's Final Office Action mailed on August 24, 2004. Claims 1-12 have been cancelled. Claims 13-17 and 20-27 are amended. Claims 13-27 are pending in the instant application and under consideration.

A. The Rejection Of Claims 13-27 Under 35 U.S.C. § 112, Second Paragraph

Claims 13-27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicants believe that this rejection is obviated and/or overcome in view of the amendment to the claims. Therefore, Applicants request that the above rejection be withdrawn.

B. The Rejection Of Claims 13, And 17-19 Under 35 U.S.C. § 102(b)

Claims 13, and 17-19 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bett *et al*, 1994, *Proceedings of the National Academy of Sciences* 91:8802-8806 ("Bett"). The rejection is respectfully traversed.

According to M.P.E.P. § 2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Applicants submit that this strict standard of identity has not been met because the Bett *et al.* does not teach vectors comprising ***adeno-associated virus*** (AAV), but rather ***adenovirus*** (AV). See Abstract (". . . we have developed a vector system based on use of ***Ad5*** [adenovirus 5] DNA sequences cloned in bacterial plasmid." Bett al at does not mention or suggest the use of AAV viruses.

The rejected claims are directed to vectors comprising both an adeno-associated virus (AAV) nucleic acid sequence and an AAV helper virus sequence (e.g., an AV) for

developing AAV viral particles. As Bett *et al.* does not disclose all of the elements of the claimed invention, the rejection of Claims 13, and 17-19 under 35 U.S.C. § 102(b) as being anticipated by Bett should be withdrawn.

C. The Rejection Of Claims 13, 17-20, And 24 Under 35 U.S.C. § 103(a)

Claims 13, 17-20, and 24 are rejected under 35 U.S.C. § 103(a) as being obvious over Bett and United States Patent No. 6,004,797 by Colosi *et al.* ("Colosi"). The rejection is respectfully traversed.

Neither Bett *et al.* nor Colosi *et al.* teach or suggest a single vector comprising an AAV nucleic acid sequence and an AAV helper virus sequence, wherein the AAV helper virus sequence comprises the complete adenovirus 5 sequence with exception of the E1 region. Moreover, neither Bett nor Colosi suggest or motivate one or ordinary skill in the art to combine the two references to achieve the claimed invention.

In fact, Bett is not concerned with the production of AAV, but merely the construction of adenoviral vectors (Ad vectors). The present invention, to the contrary of Bett et al., involves the production of vectors comprising both AAV nucleic acid sequence and adenoviral nucleic acid sequences lacking the E1 gene. Bett et al. does not teach that AAV nucleic acid sequences and helper virus sequences with a deletion of E1 can be present on a single plasmid. In this context, we refer to the discussion on page 8805 of Bett as well as Fig. 3, showing that in Bett, for the preparation of AAV particles, the 293 cells were transfected with *two* independent plasmids: the first containing all essential Ad5 sequences and the second containing the packaging signal.

Colosi, like Bett, fails to suggest or motivate the use of both AAV nucleic acid sequence and AAV helper virus sequence on the same plasmid or vector. In fact, Colosi et al. teaches the independent introduction of AAV vector and AAV helper construct into the cell. See Column 5, lines 46-57, stating that the "methods generally entail (1) introducing an AAV vector

into a suitable host cell; [and] (2) introducing an AAV helper construct into the cell . . .''). In light of the above teachings, it would not have been obvious to one or ordinary skill in the art to use a nucleic acid sequence comprising both AAV nucleic acid sequence and AAV helper nucleic acid sequence to produce AAV particles.

In view of the above, the rejection under 35 U.S.C. § 103(b) over Bett and Colosi should be withdrawn.

CONCLUSION

In view of the above amendments and remarks, the subject application is believed to be in good and proper order for allowance. Early notification to this effect is earnestly solicited.

If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 565-3585. The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit Account No. 23-2415 (Attorney Docket No. 31304-704.831) for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

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Dated: March 21, 2005 By: 

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